DYNAMIC STUDY OF THE FEET IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND THE DESIGN OF INDIVIDUAL ORTHOPEDIC INSOLES CONSIDERING LOCALLY OVER-PRESSURE AREAS

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DYNAMIC STUDY OF THE FEET IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND THE DESIGN OF INDIVIDUAL ORTHOPEDIC INSOLES CONSIDERING LOCALLY OVER-PRESSURE AREAS

ABSTRACT. This paper presents a dynamic study of the feet of patients with type 2 diabetes mellitus, as well as the design and manufacture of individual orthopedic insoles, taking into account locally overpressure areas. As a result of pedographic investigation, overpressure areas in the plantar side of the diabetic foot were identified. These locally overpressure areas were marked on the pedogram by curves when the pressure exceeded 150 kPa. A mathematical approach based on integral curves derived from the solution to Dirichlet singular boundary problem was applied to describe the overpressure areas with high precision. Based on the proposed mathematical algorithm, the software package was developed. Individualized orthopedic insoles were manufactured using silicone polymers and ethylene-vinyl acetate polymers of varying degrees of hardness. Soft polymer composites were used for locally overpressure areas, while relatively rigid material for the insole frame providing stability. Individual orthopedic insoles were produced on a computer numerical control milling machine taking into account locally overpressure areas. Individual orthopedic insoles manufactured using these technologies effectively reduce locally overloaded areas on the plantar surface of the foot and protect the foot from mechanical damage. The production and practical use of individual orthopedic insoles, developed on the basis of the research findings, contribute to the effective treatment and prevention of complications in patients with diabetic foot.
KEYWORDS: diabetic foot, foot plantar pressure area, pedograph method, individual orthopedic insoles.

STUDIU DINAMIC AL PICIOARELOR LA PACIENȚII CU DIABET ZAHARAT DE TIP 2 ȘI PROIECTAREA BRANȚURILOR ORTOPEDICE PERSONALIZATE, ȚINÂND CONT DE ZONELE DE SUPRAPRESIUNE LOCALĂ

REZUMAT. Lucrarea de față prezintă un studiu dinamic al picioarelor pacienților cu diabet zaharat de tip 2, precum și proiectarea și fabricarea unor branțuri ortopedice personalizate, ținând cont de zonele de suprapresiune locală. În urma investigației pedografice, au fost identificate zone de suprapresiune în zona plantară a piciorului diabetic. Aceste zone de suprapresiune locală au fost marcate pe pedogramă prin curbe atunci când presiunea depășea 150 kPa. Pentru a descrie zonele de suprapresiune cu o precizie ridicată, s-a aplicat o abordare matematică bazată pe curbe integrale derivate din soluția la problema Dirichlet. Pe baza algoritmului matematic propus, s-a dezvoltat un pachet software. Branțurile ortopedice personalizate au fost fabricate utilizând polimeri pe bază de silicon și polimeri de etilen-acetat de vinil cu grade variabile de duritate. Pentru zonele cu suprapresiune locală s-au utilizat compozite polimerice moi, în timp ce pentru structura branțului s-a folosit un material relativ rigid care să asigure stabilitate. Branțurile ortopedice personalizate au fost realizate pe o mașină de frezat cu comandă numerică computerizată, ținând cont de zonele cu suprapresiune locală. Branțurile ortopedice personalizate fabricate cu ajutorul acestor tehnologii reduc în mod eficient zonele suprasolicitate local de pe suprafața plantară a piciorului și protejează piciorul de leziuni mecanice. Fabricarea și utilizarea practică a branțurilor ortopedice personalizate, dezvoltate pe baza rezultatelor cercetării, contribuie la tratarea eficientă și la prevenirea complicațiilor la pacienții cu picior diabetic.
CUVINTE CHEIE: picior diabetic, zona de presiune plantară a piciorului, metoda pedografică, branțuri ortopedice personalizate.

ÉTUDE DYNAMIQUE DES PIEDS CHEZ LES PATIENTS ATTEINTS DE DIABÈTE DE TYPE 2 ET CONCEPTION DE SEMELLES ORTHOPÉDIQUES SUR MESURE TENANT COMPTE DES ZONES DE SURPRESSION LOCALE

RÉSUMÉ. Cet article présente une étude dynamique des pieds de patients atteints de diabète de type 2, ainsi que la conception et la fabrication de semelles orthopédiques sur mesure, en tenant compte des zones de surpression locale. Une analyse podographique a permis d'identifier des zones de surpression sur la face plantaire du pied diabétique. Ces zones de surpression locale ont été marquées sur le pédogramme par des courbes lorsque la pression dépassait 150 kPa. Une approche mathématique basée sur des courbes intégrales dérivées de la solution du problème aux limites singulières de Dirichlet a été appliquée pour décrire les zones de surpression avec une grande précision. Un logiciel a été développé à partir de l'algorithme mathématique proposé. Des semelles orthopédiques sur mesure ont été fabriquées à partir de polymères de silicone et de polymères d'éthylène-acétate de vinyle présentant différents degrés de dureté. Des composites polymères souples ont été utilisés pour les zones de surpression locale, tandis qu'un matériau relativement rigide a été employé pour la structure de la semelle intérieure afin d'assurer sa stabilité. Les semelles orthopédiques sur mesure ont été fabriquées sur une fraiseuse à commande numérique, en tenant compte des zones de surpression locale. Grâce à ces technologies, ces semelles orthopédiques sur mesure réduisent efficacement les zones de surpression locale sur la plante du pied et le protègent des traumatismes mécaniques. La fabrication et l'utilisation pratique de semelles orthopédiques sur mesure, mises au point à partir des résultats de la recherche, contribuent au traitement efficace et à la prévention des complications chez les patients atteints de pied diabétique.
MOTS-CLÉS : pied diabétique, zone de pression plantaire, méthode pédographique, semelles orthopédiques sur mesure.

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INTRODUCTION

Diabetes mellitus (DM) is one of the most prevalent diseases worldwide. According to the International Diabetes Federation (IDF), diabetes currently affects over 9.3% of the global population. This figure is expected to rise from 10.2% to 10.9% between 2030 and 2045, respectively [1]. One of the most severe, destructive, and irreversible complications of diabetes is the development of diabetic foot ulcer (DFU). Up to 25% of individuals with diabetes mellitus may develop diabetic foot syndrome [2, 3]. Approximately within a year after the diagnosis of DFU, patients undergo major (10%) and minor (19%) lower-limb amputations due to unsatisfactory treatment outcomes [4].

Based on the dynamics of human movement during walking and running relatively less load falls on the medial part of the foot. However, in patients with DM, ulcers more frequently develop in the anterior and medial areas of the foot than in the heel. At the same time, when ulcers develop in the heel area, the survival rate of the lower limb is 2-3 times lower [5, 6].

Considering the biomechanics of human motion, the heel initially contacts the supporting surface, then the midfoot, and finally toe joints and toes. The foot acts as an effective shock absorber to reduce the load on the skeletal system of the lower limb [7-9]. Histologically, the plantar fat pads consist of microglobules embedded within the fibroelastic septa. The plantar fat cells and the configuration of the surrounding fibrous membrane are essential for the foot to resist the external compressive loads during the stance phase and gait [10, 11].

In patients with diabetic foot, the histomorphology of the plantar fascia undergoes significant changes. Specifically, the collagen network loses its integrity, elastin fibers become degraded and fragmented, and the number of adipocytes is reduced. These changes are directly related to the widespread damage of the soft tissues of the foot and increased vulnerability [12-14].

To prevent the formation of soft tissue ulcers on the plantar part of the foot and related complications in patients with diabetes, various designs of orthopedic shoes and individual orthopedic insoles have been developed. These designs are primarily aimed at reducing peak loads on the plantar part of the foot.

The effect of reduction of overpressure on localized areas of the plantar part of the diabetic foot is widely recognized as a key indicator for assessing the treatment effectiveness [15-18]. According to the literature [19], more than 42% of diabetic foot amputations are caused by wearing ill-fitting footwear and improperly designed insoles. Consequently, peak loads in ulcer-risk areas can be substantially reduced through the use of properly designed individual orthopedic insoles.

In the treatment of patients with diabetic foot, orthopedic insoles manufactured from homogeneous material often fail to achieve the desired therapeutic effect. For effective treatment, individual orthopedic insoles fabricated from a combination of materials with various degree of hardness are necessary. In particular, soft polymeric materials should be used in overpressure areas of the plantar surface to provide pressure relief, whereas relatively rigid polymeric materials should be used for the main frame of the insoles.

The purpose of this work is to study the diabetic foot under dynamic conditions and to design and manufacture individual orthopedic insoles composed of materials with different hardness, with account of the peak loads on the plantar part of the foot. To achieve this goal, the following objectives were set:

- to study the diabetic foot using the pedograph method;
- to identify the overpressure areas on the pedograms using curved lines, where the pressure exceeds 150 kPa;
- to describe complex geometric shapes of curves defining overpressure areas using mathematical research methods;
- to develop software packages based on the proposed mathematical algorithms;

- to select suitable combinations of polymer materials with varying hardness for manufacturing orthopedic insoles;
- to produce individual orthopedic insoles from a package of polymer materials on a CNC milling machine.

RESEARCH METHODS AND MATERIALS

Study Population

The study population included 15 male patients aged 45–60 years with diagnosed diabetic foot syndrome and a disease duration exceeding 10 years. Inclusion criteria comprised the presence of plantar hyperkeratosis and diabetic foot ulcers. All patients were overweight, with body weight ranging from 100 to 140 kg. All participants provided informed consent to participate in the study.

The proposed methodology was applied to all patients included in the study.

Foot Anthropometric Research Method

At the first stage of the study, we established the clinical diagnoses, body mass index BMI and foot pathologies of the patient group. In the subsequent stage, a foot anthropometric examination was performed according to the scheme presented in Fig. 1.

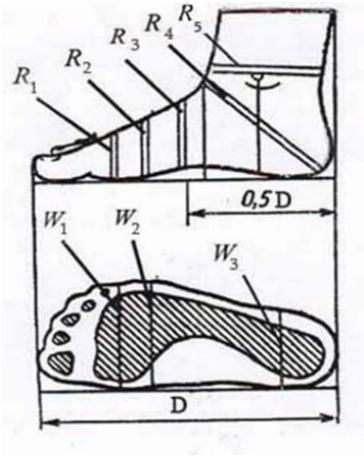


Figure 1. Anthropometric measurement scheme of the foot

Based on this examination, the following parameters were determined: foot size D, midfoot size 5D, foot width at the medial ball region W_1, foot width at the lateral ball region W_2, heel width W_3, foot girth at the medial ball region R_1, foot girth at the lateral ball region R_2, midfoot girth R_3, oblique foot girth R_4, and foot girth at the malleolus center R_5.

Mathematical Research Method

The significant novelty of this research consists in the fact that complex geometric shapes of locally overpressure areas were described on patients' pedograms by integral curves of the solutions to Dirichlet singular boundary problem [20-22].

The overloaded zones of the plantar part of the foot (hyperkeratosis/ulcer areas) have very complex, non-standard, and curvilinear geometric shapes, the description of which is impossible using conventional geometric figures (circles or ellipses). To describe the geometric curves of complex shapes, we considered various types of integral curves of solutions to first- and second-order differential equations, including the integral curves of solutions to the Dirichlet singular boundary value problem. To describe the complex geometric shapes of the curvilinear contours of locally overloaded areas of the plantar part of the foot, the integral curves of solutions to the Dirichlet singular boundary value problem were chosen, as they allow us to describe geometric contours of complex shapes with high precision. By varying the coefficient c (c = 0, 1, 2, 3, 4, 5) in the solution of the Dirichlet singular boundary value problem, a set of curvilinear curves of varying complexity is obtained.

The Dirichlet singular boundary problem is presented below:

$$u''(t) + \frac{a}{t}u'(t) - \frac{a}{t^2}u(t) = f\big(t, u(t), u'(t)\big) \quad (1)$$

$$u(t) = 0, \quad u'^{(t)} = 0, \quad (2)$$

where $a \in (-\infty; 1), f$ satisfies the local Carathéodory condition for a set $[0, t] \times D$, $\mathrm{D} = (0; +\infty) \times \mathrm{R}$.

The solution to problems (1) - (2) is expressed in the form of functions (3) and (4):

$$u(t) = \frac{t^3}{2} - \frac{1}{3}ct^{-2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2}, \quad (3)$$

$$u(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (4)$$

The corresponding integral curves of functions (3) and (4) are presented in Figure 2 and Figure 3.

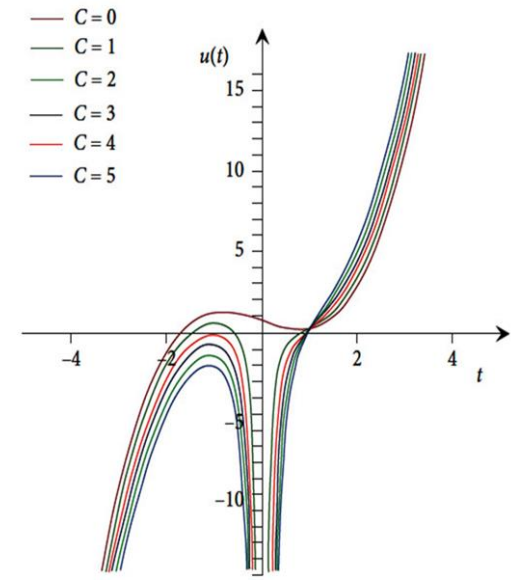


Figure 2. Integral curves of the solution to problem (3), when c=0; 1; 2; 3; 4; 5

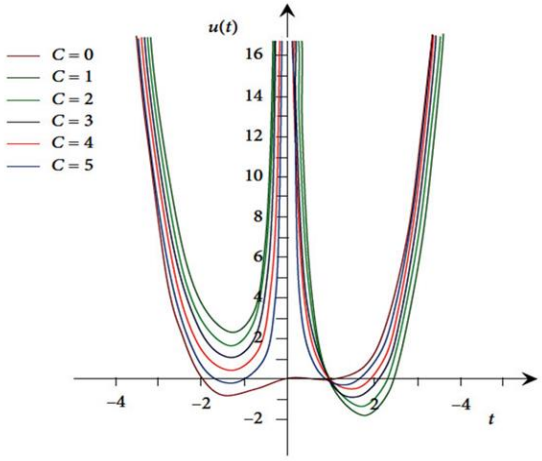


Figure 3. (4) Integral curves of the solution to problem (4), when c=0; 1; 2; 3; 4; 5

Using the above curves, we described geometric shapes of the curves of locally overpressure areas on the pedograms.

Research novelty lies in the use of a mathematical algorithm based on integral circles for solving the Dirichlet singular boundary-value problem. This approach allows highly accurate modeling of the complex geometric shapes of overloaded plantar pressure zones. Unlike existing software, which primarily visualizes pressure distribution, this method enables precise computer-aided design of these overload zones and their direct integration into the manufacturing of individualized orthopedic insoles, ensuring that material hardness are optimized for each patient.

Pedograph Research Method

The pedograph method provides important information on dynamic pressure of the plantar side of the foot. It is used to determine and record the following parameters: pressure distribution on the foot plantar surface during locomotion, peak pressure, arch index, time of contact of the foot with pedograph surface and pressure-time integral. All these parameters are calculated automatically. Information is reflected as an image of the foot with different color spectra. Pedographic examination of patients with diabetic foot was performed using the Emed-25 pedograph at/D manufactures by the Novel company (Germany).

Materials

Manufacturing individual orthopedic insoles for patients with diabetic foot using only homogeneous polymer material does not yield the desired result. For local pressures on the plantar side of the foot, soft polymer materials should be used, while relatively rigid materials are required to ensure stability of the main frame of the insole. In areas affected by diabetic foot ulcers, the use of ultra-soft polymer materials is recommended. This combination of composite polymer materials reduces the risk of ulcer development and provides fairly effective outcomes in diabetic foot treatment.

During the production of individual orthopedic insoles for overpressure areas of the diabetic foot, we used EVA polymers of various degrees of hardness from 15 to 20 Shore A. EVA polymer with a hardness of 40-45 Shore A was used for the main frame of the insoles, and ultra-soft leather-like silicone-based materials with a hardness of 5-10 Shore A were used in areas affected by diabetic foot ulcers.

The selection of material hardness was performed individually for each patient. The

choice was based on peak plantar pressure values, anatomical location of overpressure zones, condition of soft tissues, and patient-reported comfort. This approach combines quantitative pedographic data with clinical judgment.

RESEARCH RESULTS

A total of 15 patients (males, aged 45-60 years) diagnosed with diabetic foot syndrome and with a disease duration of 10 years or more, were enrolled in this study. All of them had hyperkeratosis and diabetic foot ulcers on the plantar part of the foot. All patients were overweight, with an average weight ranging from 100 to 140 kg. The clinical diagnosis, type of foot deformity, foot pathology, location, peak pressure, and body mass index (BMI) were assessed for 15 patients participating in the study. The data are presented in Table 1.

Table 1: Clinical data of the patients

Patient №	Diagnosis	Type of foot deformity		Plantar Pathology, Location, Peak Pressure		Body mass index BMI
		Left foot	Right foot	Left foot	Right foot	
1	2	5	6	7	8	9
1	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 3 flat foot	Stage 2 flat foot	Hyperkeratosis of the MTP joints Peak pressure 650 Kpa. Diabetic foot ulcer of the midfoot Peak pressure 380 Kpa.	Hyperkeratosis of the MTP joints Peak pressure 310 Kpa. Hyperkeratosis of the heel Peak pressure 340 Kpa.	41.4
2	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 2 flat foot	Stage 2 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 420 Kpa. Hyperkeratosis of the heel Peak pressure 385 Kpa.	Hyperkeratosis of the MTP joints Peak pressure 310 Kpa. Hyperkeratosis of the heel Peak pressure 410 Kpa.	38.5
3	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 3 flat foot	Stage 3 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 635 Kpa. Hyperkeratosis of the heel Peak pressure 735 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 640 Kpa. Hyperkeratosis of the heel Peak pressure 765 Kpa.	44.2
4	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 1 flat foot	Stage 1 flat foot	Hyperkeratosis of the MTP joints Peak pressure 335 Kpa. Hyperkeratosis of the heel Peak pressure 370 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 360 Kpa. Hyperkeratosis of the heel Peak pressure 395 Kpa.	37.8
5	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 2 flat foot	Stage 2 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 520 Kpa. Hyperkeratosis of the heel Peak pressure 670 Kpa.	Hyperkeratosis of the MTP joints Peak pressure 570 Kpa. Hyperkeratosis of the heel Peak pressure 685 Kpa.	43.4

Patient №	Diagnosis	Type of foot deformity		Plantar Pathology, Location, Peak Pressure		Body mass index BMI
		Left foot	Right foot	Left foot	Right foot	
1	2	5	6	7	8	9
6	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 3 flat foot	Stage 3 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 580 Kpa. Hyperkeratosis of the heel Peak pressure 620 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 610 Kpa. Hyperkeratosis of the heel Peak pressure 655 Kpa.	43.8
7	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 3 flat foot	Stage 3 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 310 Kpa. Hyperkeratosis of the heel Peak pressure 350 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 340 Kpa. Hyperkeratosis of the heel Peak pressure 380 Kpa.	39.2
8	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 3 flat foot	Stage 3 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 410 Kpa. Hyperkeratosis of the heel Peak pressure 455 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 4250 Kpa. Diabetic foot ulcer of the heel Peak pressure 510 Kpa.	42.5
9	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 2 flat foot	Stage 3 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 430 Kpa. Hyperkeratosis of the heel Peak pressure 490 Kpa.	Hyperkeratosis of the MTP joints Peak pressure 405 Kpa. Hyperkeratosis of the heel Peak pressure 395 Kpa. Diabetic foot ulcer of the midfoot Peak pressure 465 Kpa.	43.9
10	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 2 flat foot	Stage 2 flat foot	Hyperkeratosis of the MTP joints Peak pressure 330 Kpa. Hyperkeratosis of the heel Peak pressure 370 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 360 Kpa. Hyperkeratosis of the heel Peak pressure 385 Kpa.	42.7
11	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 1 flat foot	Stage 2 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 340 Kpa. Hyperkeratosis of the heel Peak pressure 380 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 360 Kpa. Hyperkeratosis of the heel Peak pressure 390 Kpa.	38.1
12	Type 2 diabetes mellitus; diabetic peripheral neuropathy;	Stage 3 flat foot	Stage 3 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 680 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 695 Kpa.	44.2

Patient №	Diagnosis	Type of foot deformity		Plantar Pathology, Location, Peak Pressure		Body mass index BMI
		Left foot	Right foot	Left foot	Right foot	
1	2	5	6	7	8	9
	neuroischemic diabetic foot			Hyperkeratosis of the heel Peak pressure 710 Kpa.	Diabetic foot ulcer of the heel Peak pressure 745 Kpa.	
13	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 3 flat foot	Stage 3 flat foot	Hyperkeratosis of the MTP joints Peak pressure 845 Kpa. Diabetic foot ulcer of the midfoot Peak pressure 880 Kpa.	Diabetic foot ulcer of the MTP joints Peak pressure 835 Kpa. Hyperkeratosis of the heel Peak pressure 790 Kpa.	44.7
14	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 2 flat foot	Stage 2 flat foot	Hyperkeratosis of the MTP joints Peak pressure 410 Kpa. Hyperkeratosis of the heel Peak pressure 470 Kpa.	Hyperkeratosis of the MTP joints Peak pressure 425 Kpa. Diabetic foot ulcer of the heel Peak pressure 485 Kpa.	38.4
15	Type 2 diabetes mellitus; diabetic peripheral neuropathy; neuroischemic diabetic foot	Stage 3 flat foot	Stage 2 flat foot	Diabetic foot ulcer of the MTP joints Peak pressure 450 Kpa. Hyperkeratosis of the heel Peak pressure 510 Kpa.	Hyperkeratosis of the MTP joints Peak pressure 490 Kpa. Hyperkeratosis of the heel Peak pressure 530 Kpa.	41.5

The table presents the clinical data of 15 patients, whose main characteristics are as follows: all patients present with type 2 diabetes mellitus, diabetic peripheral neuropathy, and neuroischemic diabetic foot. The patients predominantly exhibit second- and third-stage flat foot on both feet, with first-stage flat foot occurring only in rare cases. Foot pathologies (ulcers, hyperkeratosis) are mainly localized in the metatarsophalangeal joint region and the heel region, and rarely in the midfoot area. As seen from the table, the peak plantar pressure values are extremely high in all cases, representing risk zones for the pathology. The body mass index (BMI) of the patients is high, ranging from 37.8 to 44.7, which reflects overweight or class 3 obesity.

At the next stage of the study, the patients' anthropometric data were evaluated. The results are presented in Table 2.

Table 2: Anthropometric data of the patients with diabetic foot

Patient №	D Foot size	W_1 Foot width at the medial ball region, mm	W_2 Foot width at the lateral ball region, mm	W_3 Heel width, mm	R_1 Foot girth at the medial ball region, mm	R_2 Foot girth at the lateral ball region, mm	R_3 Midfoot girth, mm	R_4 oblique foot girth, mm	R_5 Foot girth at the malleolus center, mm
1	2	3	4	5	6	7	8	9	10
1	44	118	127	94	289	291	315	398	315
2	42	112	119	82	279	285	301	378	308
3	45	121	129	102	298	304	315	421	401
4	41	108	113	78	268	275	287	354	291
5	43	117	122	99	285	287	314	385	297

Patient №	D Foot size	W_1 Foot width at the medial ball region, mm	W_2 Foot width at the lateral ball region, mm	W_3 Heel width, mm	R_1 Foot girth at the medial ball region, mm	R_2 Foot girth at the lateral ball region, mm	R_3 Midfoot girth, mm	R_4 oblique foot girth, mm	R_5 Foot girth at the malleolus center, mm
1	2	3	4	5	6	7	8	9	10
6	43	119	125	101	286	288	316	387	296
7	42	114	121	86	285	288	304	382	312
8	44	121	129	97	293	297	318	401	319
9	44	118	127	94	289	291	315	398	315
10	43	121	128	110	288	293	318	395	311
11	42	112	119	84	276	287	301	379	305
12	45	124	133	109	303	312	318	428	406
13	46	128	138	128	316	324	336	425	437
14	42	110	116	81	273	281	299	374	302
15	43	118	126	108	286	289	314	387	308

The majority of patients have medium to large foot sizes (predominantly ranging from 42 to 44), which demonstrates a normal distribution of sizes within the study group. The foot width at the medial ball region ranges from 108 mm to 128 mm, at the lateral ball region from 113 mm to 138 mm, and at the heel from 78 mm to 128 mm; these values exceed standard measurements in all cases. The foot girths at the medial and lateral regions are 268–316 mm and 275–324 mm, respectively. In diabetic foot conditions, these zones are particularly sensitive to pressure and ulcer formation. The oblique foot girth ranges from 354 mm to 428 mm, characterized by the highest numerical values, which reflect the volumetric dimensions of the foot in an oblique direction. The foot girth at the malleolus center ranges from 291 mm to 437 mm, indicating the volume of the ankle and lower leg region.

This paper considers the results of a detailed examination of the foot of Patient 1 presented in Table 1, along with the process of design and manufacturing of individual orthopedic insoles. The patient was diagnosed with Type 2 diabetes mellitus, diabetic peripheral neuropathy, and neuroischemic diabetic foot. The patient was 58 years old, weighing 137 kg, with a height of 182 cm, a body mass index of 41.4, a foot size of 44, and was classified as third-degree obesity. Figure 4 presents the pedogram of this patient.

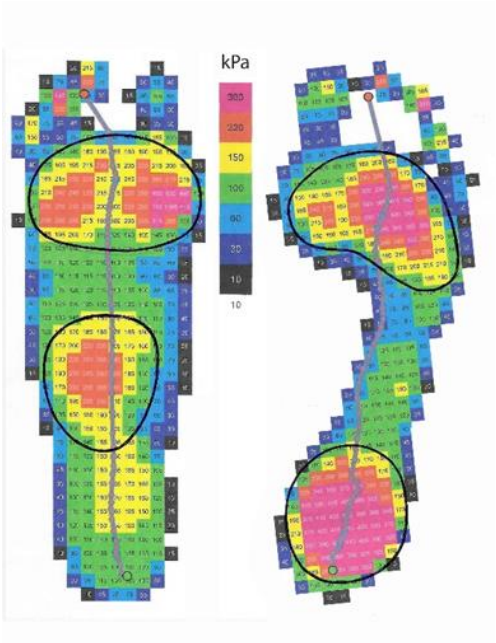


Figure 4. The pedogram of a patient with diabetic foot

The patient's clinical data and the analysis of pedogram shown in Figure 4 indicate third degree flatfoot of the left foot. Hyperkeratosis is observed in metatarso-phalangeal (MTP) joint area of the plantar part of the foot. The highlighted area on the pedogram indicates overpressure areas, marked in red and yellow, with pressures ranging from 180 to 650 Kpa. This area is at risk of disease complications and ulceration. The pressure in the mid-plantar region of the left foot ranges from 180 to 380 Kpa (overpressure area) indicating a diabetic foot ulcer. This area is also marked in red and yellow on the pedogram.

The analysis of the right foot revealed that the patient had second-degree flatfoot. Hyperkeratosis was observed in the metatarsophalangeal (MTP) joints of the plantar part of the foot and in the heel area. The region marked in red and yellow on the pedogram indicate overpressure area, where the pressures per unit area is 170-340 Kpa, representing a high risk for complications and ulcer development.

The locally overpressure areas are marked with curves, which showed the pressure of 150 Kpa and over (Figure 4). The description of the presented curves was carried out by means of integral curves of the solutions to Dirichlet singular boundary problem.

Since the contour of the overloaded zone of the plantar part of the foot is complex and non-uniform, a single mathematical function and a single integral curve of its solution cannot fit the entire figure. Therefore, the contour of each overloaded zone is divided into individual segments depending on the sharpness of the contour curvature in different areas. The corresponding integral curves were fitted to each segment individually by varying the coefficients c.

Existing software simply visualizes the overpressure areas through a color spectrum on a pedogram, but does not provide their exact geometric model or the ability to transfer them to a CNC machine. In contrast, this method provides millimeter-precision of the overloaded zones through their computer-aided design and direct integration into the CNC milling process.

Figure 5 the geometric shape of the curve of a locally overpressure area of the MTP of the plantar part of the left foot, which was taken from the pedogram (Figure 4).

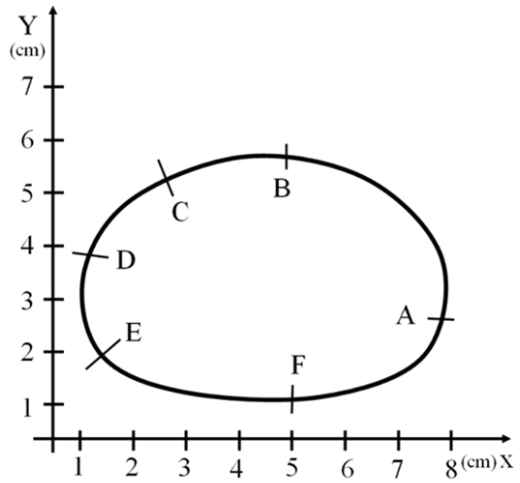


Figure 5. Geometric shape of the curve of the overpressure area of the MTP joints of the plantar part of the left foot

The curve illustrated in Figure 5 was preliminarily divided into six parts. Each numbered region was described using the integral curves of the functions given below. Six parts of the integral curves identically corresponding to the geometric shapes of the curve on the overpressure area of the plantar side of the MTP of the left foot were chosen, namely the following:

1. AB - curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (5)$$

for which c = 0 and corresponds to a set [0,1;0,7] × [-2,5; -5,0]

2. BC - curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (6)$$

for which c = 5 and corresponds to a set [-1,5; -1,5] × [-7,0; -2.2]

3. BC - curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (7)$$

for which c = 0 and corresponds to a set [-1,2; 2; 1,0] × [-2,1; -2,0]

4. DE - curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (8)$$

for which *c* = 1 and corresponds to a set [-1,0; -0,1] × [-0.4; 2.2]

5. EF – curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (9)$$

for which *c* = 0 and corresponds to a set [1,6; 0,3] × [2,5; 5,5]

6. FA – curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (10)$$

for which *c* = 5 and corresponds to a set [-11,9; 5,0] × [-2.3; 6,0].

Based on the above-mentioned mathematical algorithm, the software was developed to describe the curve segments. By rotating and translating these curves, an exact geometric shape of the curve was obtained to represent the locally overpressure areas in MTP region of the plantar surface of the left foot.

Figure 6 shows the geometric shape of the curve of the locally overpressure area of the middle of the plantar part of the left foot, taken from the pedogram (Figure 4).

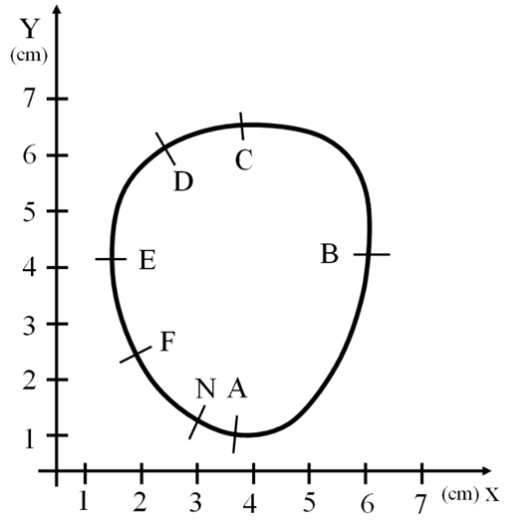


Figure 6. The shape of the curve of the locally overpressure area of the middle of the plantar part of the left foot

The curve shown in Figure 6 was preliminarily divided into 7 parts. Each numbered section was described using the integral curves of the functions given below. From these integral curves, 7 parts identically corresponding to the geometric shapes of the curve of overpressure area in the middle of the plantar part of the left foot were chosen, namely:

1. AB - curve corresponds to that part of the solution to equation

$$u(t) = \frac{t^3}{2} - \frac{1}{3}ct^{-2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2}, \quad (11)$$

for which *c* = 0 and corresponds to a set [0.9; -0.5] × [-2,5; -5,0]

2. BC - curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (12)$$

for which *c* = 0 and corresponds to a set [-0,2; -0,1] × [1,5; -2,4]

3. CD - curve corresponds to that part of the solution to equation

$$u(t) = \frac{t^3}{2} - \frac{1}{3}ct^{-2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2}, \quad (13)$$

for which *c* = 5 and corresponds to a set [-1,4; -2,4] × [-2,0; -4,9]

4. DE - curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (14)$$

for which *c* = 1 and corresponds to a set [-1,2; -0,1] × [-0,4; -1,1]

5. EF - curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (15)$$

for which *c* = 5 and corresponds to a set [-1,1; 2,1] × [2,5;1,1]

6. FN – curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (16)$$

for which c = 0 and corresponds to a set [1,4; 0,1] × [2,1; 1,9]

7. NA - curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (17)$$

for which c = 0 and corresponds to a set [-1,6; 0,1] × [-1,0; -1,8]

Based on the mathematical algorithm, computer programs describing curves were developed. By rotating and translating the curves, a precise geometric shape was obtained to represent the locally overpressure area in the middle part of the left foot.

Similarly, we constructed complex geometric shapes for the overpressure area of the plantar part of the right foot and the heel.

Figure 7 shows a complex geometric shape of the overpressure area in the plantar part of the MTP joints of the right foot taken from the pedogram (Figure 4).

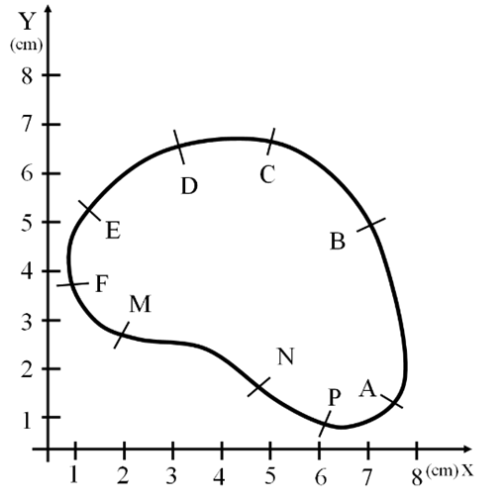


Figure 7. Geometric shape of the curve of the overpressure area of the MTP joints of the plantar part of the right foot

The curve shown in Figure 7 was preliminarily divided into nine segments. Each section was described using the integral circles of the functions listed below. From the integral curves, nine sections of the integral curves identically corresponding to the complex geometric shapes of the curve of the overpressure area at the point of MTP joints of the plantar part of the right foot were chosen, namely the following:

1. AB - curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (18)$$

for which c = 0 and corresponds to a set [1,0; -1,1] × [-2,5; -5,1]

2. BC - curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (19)$$

for which c = 5 and corresponds to a set [-1,4; -2,9] × [-2,0; -5,1]

3. CD - curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6} \quad (20)$$

for which c = 5 and corresponds to a set [-1,0; 2,5] × [-0,5; 5,5]

4. DE – curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6}, \quad (21)$$

for which c = 0 and corresponds to a set [1,5; 0,2] × [2,2; 3,1]

5. EF – curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6}, \quad (22)$$

for which c = 1 and corresponds to a set [-1,1; -0,1] × [-0,5; 1,9]

6. FM – curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (23)$$

for which c = 1 and corresponds to a set [-1,2; 0,1] × [-1.8; 0,1]

7. MN – curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6}, \quad (24)$$

for which c = 0 and corresponds to a set [-0,8; -1,1] × [1,0; 0,1]

8. NP – curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6}, \quad (25)$$

for which c = 5 and corresponds to a set [-1,2; 2,1] × [2,5; 1,0]

9. PA – curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (26)$$

for which c = 4 and corresponds to a set [-5,8; -0,5] × [-1,8; -1,0].

Based on the mathematical algorithm, computer programs were developed to describe the curves. By rotating and translating these curves, we got complex geometric shape of the curve of the locally overpressure area on the MTP of the right foot's plantar surface, which is an exact analogue of the complex geometric curved line shown on the pedogram.

Similarly, we constructed complex geometric shapes for the overpressure area of the plantar part of the heel of the right foot.

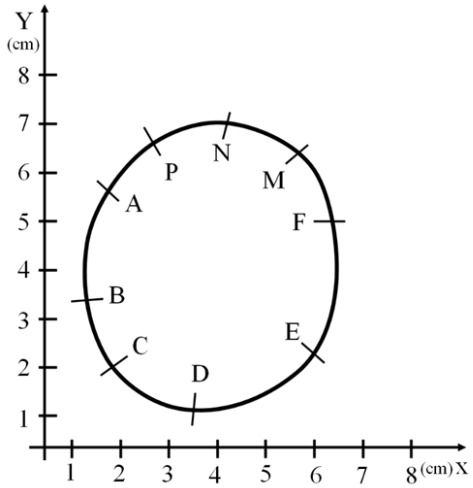


Figure 8. Geometric shape of the curve of the locally overpressure area in the heel area of the plantar part of the right foot

Figure 8 shows the curve of a complex geometric shape of the overpressure area in the heel area of the plantar part of the right foot, taken from the pedogram (Figure 4). This curve was preliminary divided into nine parts and the description of each section using the integral curves of the functions given below.

From the integral curves, nine sections of curves were selected that identically correspond to the complex geometric shapes of the curves of the overpressure area in the heel area of the plantar part of the right foot, namely:

1. AB - curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6}, \quad (27)$$

for which c = 5 and corresponds to a set [-1,9; 2,0][2,5; 1,1]

2. BC - curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (28)$$

for which c = 5 and corresponds to a set [-2,5;-1,4][-4,9; -1,9]

3. CD – curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6}, \quad (29)$$

for which c = 0 and corresponds to a set [-2,3; 1,1][-1,8; -1,6]

4. DE – curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (30)$$

for which c = 0 and corresponds to a set [-1,8; 1,0][-2,5; -2,1]

5. EF – curve corresponds to that part of the solution to equation

$$u(t)=\frac{t^3}{2}-\frac{1}{3}ct^{-2}-\left(1-\frac{1}{3}c\right)t+\frac{1}{2}, \quad (31)$$

for which c = 0 and corresponds to a set [-1,2; 1,8][-2,1; -4,0]

6. FM – curve corresponds to that part of the solution to equation

$$u(t)=(-\frac{1}{3}-\frac{1}{3}c)t+\frac{1}{3}c\frac{1}{t^2}+\frac{2}{3}t-\frac{t^2}{2}+\frac{t^4}{6}, \quad (32)$$

for which c = 0 and corresponds to a set [1,6; 0,2][2,1; 2,1]

7. MN – curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (33)$$

for which *c* = 1 and corresponds to a set [-1,9; 0,1][-0,5; 2,1]

8. NP – curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (34)$$

for which *c* = 2 and corresponds to a set [-1,8; 0,8][-0.6; 2,2]

9. PA – curve corresponds to that part of the solution to equation

$$u(t) = (-\frac{1}{3} - \frac{1}{3}c)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t - \frac{t^2}{2} + \frac{t^4}{6}, \quad (35)$$

for which *c* = 5 and corresponds to a set [-1,0; 2,8][-0,7; 3,3].

Here, computer programs describing curves were also constructed using a mathematical algorithm. By rotating and translating these curves, we got a precise curve of the complex geometric shape of the overpressure area in the heel of the plantar part of the right foot.

Thus, through the use of integral curves of the solutions to Dirichlet singular boundary problem, it is possible to describe complex the geometric shape of a curve of any complexity with high precision. The proposed study was applied to all patients included in the group.

DISCUSSION

The process of design and manufacturing of individual orthopedic insoles is quite complicated and sequential. The curves with complex geometric shape of the locally overpressure areas taken from the pedogram are described through the integral curves of the solutions to the Dirichlet singular boundary problem. Based on the mathematical algorithm, the complete software packages were developed for the production of complex geometric shapes of overpressure areas of the plantar part of the foot.

Using the CNC milling machine, we pre-milled the overpressure areas from relatively soft materials. Specifically, for the plantar area of the left foot, where the peak pressure ranged from 180 to 650 Kpa, we chose an EVA polymer with a hardness of 15 Shore A. In the midfoot area (location of the diabetic foot ulcer, with the peak pressure 170-380 Kpa, we used a combination of polymer materials: a silicone-based, leather-like polymer with a hardness of 5 Shore A and an EVA polymer with a hardness of 15 Shore A. For the plantar area of the right foot, where the pressure is 180-340 Kpa, we chose an EVA polymer with a hardness of 40 Shore A. When selecting materials, we took into account the patient's subjective factors as much as possible.

The shapes of the overloaded areas were first milled from soft materials using a CNC milling machine. The corresponding shapes were then cut from the frame of insole using a CNC milling machine. At the next stage, the shapes of the overloaded areas were embedded into the frame of insole, resulting in the final material for manufacturing the orthotic insole.

Using the developed computer programs and a CNC machine, custom orthotic insoles were manufactured, taking into account localized overloaded areas of the plantar surfaces. The resulting insoles are shown in Figure 9.

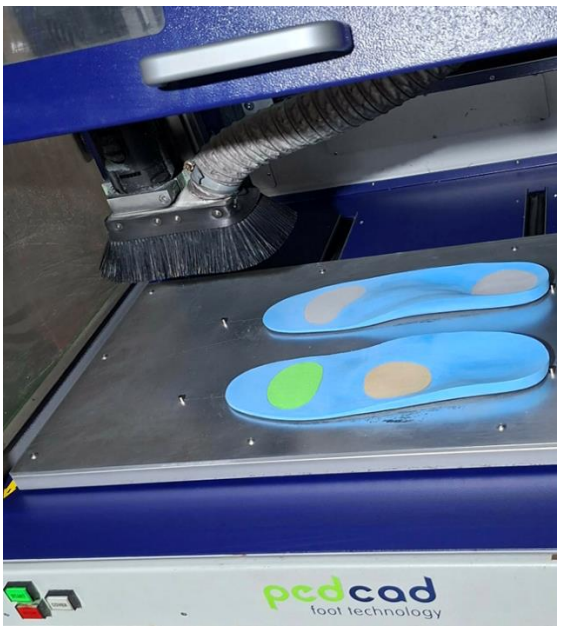


Figure 9. Individual orthopedic insoles, designed to account for the locally overpressured areas on the plantar surfaces of the feet

Figures 10 and 11 show images of individual orthopedic insoles in various projections.

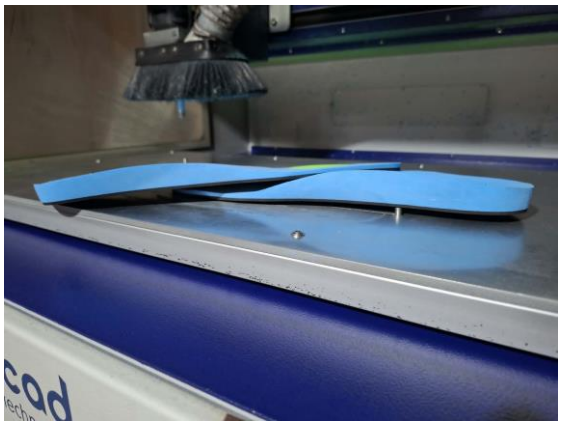


Figure 10. Insole arch parts

Figure 10 clearly shows the difference between the heights of the insole arches: the arch height of the left foot insole is 21 mm, while the arch height of the right insole is 28 mm, with a difference of 7 mm.



Figure 11. The shape of the support part of the insole

Figure 11 clearly shows the difference in shapes across the support area of the insoles.

The software package includes the following steps:

- Identification and segmentation of the zones of excessive pressure on the plantar part of the foot (demarcation using curved lines);
- Description of individual curves constituting the complex geometric shapes of the zones of excessive pressure on the pedograms using integral curves derived from the solution of the Dirichlet singular boundary-value problem, based on the corresponding mathematical algorithm;
- Geometric transformation (translation and rotation) of the curve segments to obtain accurate contours of the zones of excessive pressure;
- Development of computer programs describing the complex geometric shapes of the zones of excessive pressure based on the proposed mathematical algorithm and their implementation in the process of insole design;
- Export of the developed computer programs into formats compatible with CNC-controlled machine tools.

It should be noted that, unlike previously published studies, this work employs a mathematical research method that enables highly accurate description of the shapes of overloaded areas on the plantar surface of the diabetic foot.

Based on the conducted research, individual orthopedic insoles were manufactured for the 15 patients in the study group. The patients wore special orthopedic shoes daily, tailored to the specific anthropometric parameters of each individual's foot. The patients used the insoles in their daily footwear throughout the trial period. During the first 1–2 weeks, an intensive adaptation phase took place, accompanied by the initial compression of the EVA polymer. During this period, the material adapted to the patient's foot anatomy and load characteristics. By the 3rd–4th week of daily wear, the deformation of the EVA polymer significantly decreased, and its deformation properties transitioned into a stable phase. After 4 weeks, the subjective comfort of the individual insoles was evaluated. The majority of patients demonstrated an improved quality of life, which can be considered a positive indicator for the initial stage of observation. Long-term clinical outcomes are part of an ongoing, extended study and will be presented in future publications.

CONCLUSION

In this study, individual orthopedic insoles were designed for 15 patients with diabetic foot syndrome. For each patient, areas of excessive

plantar pressure were identified using pedograms. The complex geometric shapes of these overloaded zones were described with high accuracy using integral curves derived from the solution of a Dirichlet singular boundary-value problem. Based on the proposed mathematical algorithm, computer programs were developed and were exported into CNC-compatible formats for insole fabrication.

During the manufacturing of the insoles, EVA polymers with a hardness of 15–20 Shore A were used for overloaded areas, ultra-soft silicone-based materials with a hardness of 5–10 Shore A were applied in zones of ulcers and hyperkeratosis, and EVA polymers with a hardness of 40–45 Shore A were used for the insole frame. The selection of material hardness was based on plantar pressure values, as well as clinical data and patient-reported comfort.

Trial wear of the insoles demonstrated a reduction in peak pressure in overloaded zones, improved pressure distribution across the foot, and improvement in the clinical condition of ulcers and hyperkeratosis.

The proposed method shows that the combination of pedographic data, mathematical modeling, and the use of combined polymer materials makes it possible to design and manufacture individual orthopedic insoles that can contribute to the effective management of patients with diabetic foot syndrome.

Ethical Standards and Protection of Personal Data

All data presented in this article were collected and published in full compliance with ethical standards. No identifiable personal information is included, and every effort has been made to protect the privacy of the patients involved.

Conflicts of Interest

The authors declare that they have no conflicts of interest regarding this research.

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